



USSN: 09/528,682
Atty. Dkt. No.: PP000342.0105
2302-0342.10

PATENT

CERTIFICATE OF MAILING PURSUANT TO 37 CFR § 1.8

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8/22/05
Date

Michelle Hobson
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

PIZZA et al.

Serial No.: 09/528,682

Filing Date: March 20, 2000

Title: IMMUNOGENIC DETOXIFIED MUTANT
E. COLI LT-A TOXIN

Examiner: M. Borin

Group Art Unit: 1631

Confirmation No.: 5794

**INFORMATION DISCLOSURE STATEMENT
UNDER 37 C.F.R. §1.97(b)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sirs:

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56,
Applicant(s) hereby submits the following information in conformance with 37 C.F.R.
§§1.97 and 1.98.

- ☒ Pursuant to 37 C.F.R. §1.98, copies A1, B1 - B7 and C1 - C29 cited in the attached Form PTO/SB/08 are enclosed.
- ☐ No copy of the U.S. publication ____ listed on the attached Form PTO/SB/08A are being provided because the Office waives the requirement under 37 C.F.R. 1.98 (a) (2) (i) for submitting a copy of each cited U.S. patent and each U. S. patent application publication for all U.S. national patent applications filed after June 30, 2003
- ☐ No copies of the publications listed on the attached Form PTO/SB/08A are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application

Serial No. _____ to which the above-identified application claims priority under 35 U.S.C. §120.

- ☐ Publication(s) _____ listed on the attached Form PTO/SB/08A were cited in a foreign search or examination report corresponding to PCT application serial no. _____ and mailed on _____.
- ☐ Enclosed is a copy of a non-English publication(s) _____. Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).
- ☐ Enclosed is a copy of a non-English publication(s) _____. English language publication ____ (copy enclosed) claims priority from this non-English publication.
- ☐ Enclosed is an explanation of non-English publication(s) ____ for which an English translation is not available.
- ☐ Enclosed is an English translation of non-English publication(s) ____ cited in the attached Form PTO/SB/08A.
- ☐ Enclosed is a copy of pending patent Application Serial No. _____.

This Information Disclosure Statement is filed within any one of the following time periods:


- ☐ within three months from the filing date of this national application other than a CPA under 37 C.F.R. § 1.53(d);
- ☐ within three months from the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in this international application;
- ☐ before the mailing date of a first office action on the merits; or
- ☒ before the mailing of a first office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

This Information Disclosure Statement under 37 CFR § 1.97 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist; (iii) the information, protocols, results and the like reported by third parties are accurate or enabling; or (iv) the above information constitutes prior art to the subject invention.

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO/SB/08A to the undersigned.

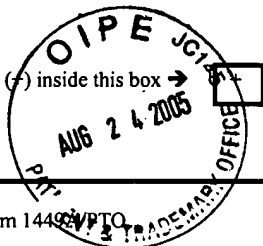
Respectfully submitted,

Date: August 22, 2005

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PTO/SB/08A (08-00)

Substitute for form 1449 PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete if Known	
Application Number		09/528,682			
Filing Date		March 20, 2000			
First Named Inventor		PIZZA et al.			
Group Art Unit		1631			
Examiner Name		M. Borin			
Attorney Docket Number		PP000342.0105			
Sheet	1	of	3		

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
	A1	5,182,109		Tamura, et al.	01-26-1993

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)			
	B1	WO	92/19265		AMGEN, INC. AND UNIVERSITY OF SOUTHERN CALIFORNIA	11-12-1992	
	B2	WO	95/09649		MEDEVA HOLDINGS B.V.	04-13-1995	
	B3	WO	95/34323		CONNAUGHT LABORATORIES LIMITED	12-21-1995	
	B4	WO	99/58145		UNIVERSITY OF BRISTOL	11-18-1999	
	B5	WO	00/18434		AMERICAN CYNAMID COMPANY	04-06-2000	
	B6	EP	0396964		SCLAVO S.P.A.	11-14-1990	
	B7	EP	0462534		SCLAVO S.P.A.	12-27-1991	

Examiner Signature	Date Considered	
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³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

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PTO/SB/08A (08-00)

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Complete if Known			
		Application Number	09/528,682		
		Filing Date	March 20, 2000		
		First Named Inventor	PIZZA et al.		
		Group Art Unit	1631		
		Examiner Name	M. Borin		
Sheet	2	of	3	Attorney Docket Number	PP000342.0105 (2300-0342.10)

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
	C1	Burnette, "The Advent of Recombinant Pertussis Vaccines." <i>Biotechnol.</i> 8:1002-1005 (1990)
	C2	Burnette, <i>Vaccine Research & Developments</i> Chapter 6, Marcel Dekker Inc., New York, New York (1992)
	C3	Communication to EPO Concerning Replacement Claims for Filing with the EPO in Application No. 99922284.7 (2003)
	C4	de Haan, et al., "Mutational Analysis of the Role of ADP-Ribosylation Activity in the Adjuvant Properties of the Escherichia Coli Heat-Labile Enterotoxin Towards Intranasally Administered Keyhole Limpet Hemocyanin." <i>Eur. J. Immunol.</i> 28:1243-1250 (1998)
	C5	Del Guidice, et al., "Genetically Derived Toxoids for use as Vaccines and Adjuvants." <i>Vaccine</i> 17:S44-S52 (1999)
	C6	Dickinson & Clements, "Dissociation of Escherichia coli heat-labile enterotoxin adjuvant activity from ADP-ribosyltransferase activity", <i>Infect. Immunity</i> , 63:1617-1623 (1995)
	C7	EPO Communication pursuant to Article 96(2) EPC relating to Application EP No. 94928455.8-2116 (2001)
	C8	"Multicomponent Vaccine Development." <i>NIH Guide</i> Volume 22, Number 28 (1993)
	C9	Green, Bruce, Curriculum Vitae
	C10	Grant et al., "Role of trypsin-like cleavage at arginine 192 in the enzymatic and cytotoxic activities of Escherichia coli heat-labile enterotoxin", <i>Infect. Immun.</i> , 62:4270-4278 (1994).
	C11	Hagen, Michael, Curriculum Vitae
	C12	Hagiwar, et al., Effectiveness and Safety of Mutant Escherichia Coli Heat-Labile Enterotoxin (LT H44A) as an Adjuvant for Nasal Influenza Vaccine." <i>Vaccine</i> 19:2071-2079 (2001)
	C13	Hartman, et al., "Native and Mutant Forms of Cholera Toxin and Heat-Labile Enterotoxin Effectively Enhance Protective Efficacy of Live Attenuated and Heat-Killed Shigella Vaccines." <i>Infect. Immun.</i> 67:5841-5847 (1999)
	C14	Hazama, et al., "Intranasal Immunization Against Herpes Simplex Virus Infection by using a Recombinant Glycoprotein D Fused with Immunomodulating Proteins, the B Subunit of Escherichia Coli Heat-Labile Enterotoxin and Interleukin-2." <i>Immunology</i> 78:643-649 (1993)
	C15	Hirst, et al., "Cholera Toxin and Related Enterotoxins as Potent Immune Modulators." <i>J. Appl. Microb. Symp. Suppl.</i> 48:26S-34S (1998)
	C16	Hirst, <i>The Comprehensive Sourcebook of Bacterial Protein Toxins</i> , Chapter 6, Academic Press, pgs. 104-130, (1999)
	C17	Lobet et al., "Effect of site-directed mutagenic alterations on ADP-ribosyltransferase activity of the A subunit of Escherichia coli heat-labile enterotoxin", <i>Infect. Immun.</i> 59:2870-2879 (1991)
	C18	Lycke, et al., "Strong Adjuvant Properties of Cholera Toxin on Gut Mucosal Immune Responses to Orally Presented Antigens." <i>Immunol.</i> 56:301-308 (1986)
	C19	Lycke, et al., "The Mechanism of Cholera Toxin Adjuvant activity." <i>Res. Immunol.</i> 198:504-520 (1997)
	C20	Martindale, <i>Royal Pharmaceutical Society of Britain</i> Pharmaceutical Press, London, England, pgs.1277-1304(1993)
	C21	Rappouli, et al., "Structure and Mucosal Adjuvant activity of Cholera and Escherichia Coli Heat-Labile Enterotoxins." <i>Immunol. Today</i> 20:493-500 (1999)
	C22	Spangler, "Structure and Function of Cholera Toxin and The Related Escherichia Coli Heat-Labile Enterotoxin." <i>Microbiol. Rev.</i> 56:622-647 (1992)
	C23	Streatfield, et al., "Intermolecular Interactions Between the A and B Subunits of Heat-Labile Enterotoxin from Escherichia Coli Promote Holotoxin Assembly and Stability In Vivo." <i>PNAS USA</i> 89:12140-12144 (1992)
	C24	<i>The Comprehensive Sourcebook of Bacterial Protein Toxins</i> , 2 nd Ed., Academic Press, pgs. 696-697
	C25	Tsuji, et al., "Relationship Between a Low Toxicity of the Mutant A Subunit of Enterotoxigenic Escherichia Coli Enterotoxin and its Strong Adjuvant Action." <i>Immunology</i> 90:176-182 (1997)

Examiner Signature		Date Considered	
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